INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/30298

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 10/00 (2007.01)
USPC - 606/159
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 10/00, A61B 17/00 (2007.01)
USPC - 606/159, 606/190

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent, IP.com, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,522,825 A (KROPF et al) 04 June 1996 (04.06.1996) entire document	1-4, 9-13, 16
Y		5-8, 14-15, 17
Y	GB 2177307 A (AMBROSE) 21 January 1987 (21.01.1987) entire document	5-8
Y	US 6,371,968 B1 (KOGASAKA et al) 16 April 2002 (16.04.2002) entire document	14-15, 17

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 July 2007	11 JAN 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Marcella D. Watkins
CONLEY ROSE, P. C.
P. O. Box 3267
Houston, Texas 77253-3267

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	11 JAN 2008
Applicant's or agent's file reference 2329-00302	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US06/30298	31 July 2006	29 July 2005

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 10/00 (2007.01)
USPC - 606/159

Applicant X-STEN, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	19 July 2007	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	5-8, 14-15, 17	YES
	Claims	1-4, 9-13, 16	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-4, 9-13 lack novelty under PCT Article 33(2) as being clearly anticipated by Kropf et al. (US 5,522,825).

Regarding claim 1, Kropf et al. disclose a device for excising tissue, comprising: an outer sleeve (7 of fig. 2); an inner tubular member slidingly received within the outer sleeve (col. 4, lines 23-24); a cutting head on a distal end of the inner tubular (10, 11, 4); wherein the cutting head comprises at least three arms extending axially from the inner tubular (10, 11, 4; see also col. 2, lines 61-62); wherein the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve; and wherein the arms are biased away from each other when the device is in the opened position (col. 3, lines 44-65).

Regarding claim 2, Knopf et al. disclose wherein the outer sleeve has an inner surface at a radius R1 (col. 3, lines 23-24) and at least one arm has an outer frustoconical surface that extends radially to a distance greater than the radius R1 when the device is in the open position (10, 11 of fig. 2).

Regarding claim 3, Knopf et al. disclose wherein the inner surface of the outer sleeve (7 of fig. 1) engages a radially outermost portion of the frustoconical surface when the device is in the closed position (10, 11).

Regarding claim 4, Knopf et al. disclose wherein each arm has a fixed end integral with the inner tubular and a free end (col. 3, lines 35-39).

Regarding claim 9, Kropf et al. disclose wherein at least one arm has an inner surface that includes a textured surface feature (proximal end 4 of fig. 1).

Regarding claim 10, Kropf et al. disclose wherein the textured surface feature comprises ridges or hurling (proximal end 4 of fig. 1).

Regarding claim 11, Kropf et al. disclose wherein the at least three arms define a tissue receiving space that is contiguous with a through bore of the inner tubular (col. 2, lines 54-56).

Regarding claim 12, Kropf et al. disclose wherein each arm has a fixed end and a free end and wherein the free end of each arm engages the free end of at least one other arm when the device is in the closed position (4, 10 and 11 of fig. 1).

Regarding claim 13, Kropf et al. disclose a method for treating stenosis in a spine of a patient having a median plane, the spine including a spinal canal having a posterior surface, a dural sac and an epidural space between the posterior surface and dural sac, the location of the stenosis determining a region of interest in the spine, comprising the steps of a) positioning a tissue excision device adjacent the region of interest (col. 2, lines 57-61), wherein the tissue excision device comprises: an outer sleeve (7 of fig. 2); an inner tubular member slidingly received within the outer sleeve (col. 4, lines 23-24); a cutting head on a distal end of the inner tubular (10, 11, 4); wherein the cutting head comprises at least three arms extending axially from the inner tubular (10, 11, 4; see also col. 2, lines 61-62); wherein the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve (col. 3, lines 44-65); b) opening the tissue excision device by extending the cutting head from the outer sleeve (col. 3, lines 44-54); c) inserting the tissue excision device into tissue in the region of interest (col. 2, lines 57-61); d) closing the tissue excision device by advancing the outer sleeve over the cutting head (col. 3, line 66-col. 4, line 10); and e) retracting the tissue excision device from the tissue in the region of interest (col. 2, lines 57-61).

Claim 16 lacks an inventive step under PCT Article 33(3) as being obvious over Kropf et al. (US 5,522,825).

Regarding claim 16, Kropf et al. discloses that as recited in claim 13. Kropf et al. does not disclose further comprising the step of emptying the cut tissue from the tissue excision device. However, Kropf et al. disclose that the cut tissue accumulates in the inner tube of the device (col. 4, lines 14-19). At the time of the invention, it would have been obvious to one skilled in the art to empty the cut tissue from the tissue excision device, as taught by Kropf et al. The motivation for doing so would have been to clean the tissue excision device between uses.

Continued in Next Supplemental Box

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Box V
Claims 5-8 lack an inventive step under PCT Article 33(3) as being obvious over Kropf et al. (US 5,522,825) in view of Ambrose (GB 2177307).

Regarding claim 5, Kropf et al. disclose wherein the free end of at least one arm includes a grasping member (col. 3, lines 8-10). However, Kropf et al. do not disclose wherein the free end of the at least one arm includes a tissue grasping member. Ambrose discloses a device for excising tissue, comprising: an outer sleeve (1 of fig. 1); an inner tubular member slidingly received within the outer sleeve (page 2, lines 8-11); a cutting head on a distal end of the inner tubular (11); wherein the cutting head comprises a plurality of arms extending from the inner tubular (11); wherein the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve (page 2, lines 20-24), wherein the free end of at least one arm includes a tissue grasping member (page 2, lines 35-39). At the time of the invention, it would have been obvious to one skilled in the art to include a tissue grasping member on the free end of at least one arm, as taught by Ambrose. The motivation for doing so would have been to enable the facile removal of tissue cut by the cutting head.

Regarding claim 6, Kropf et al. do not disclose wherein said tissue grasping member comprises a tooth extending radially inward. Ambrose discloses wherein said tissue grasping member comprises a tooth extending radially inward (page 2, lines 35-39). At the time of the invention, it would have been obvious to one skilled in the art to use as a tissue grasping member a tooth extending radially inward, as taught by Ambrise. The motivation for doing so would have been to simplify the manufacturing process of the tissue grasping device.

Regarding claim 7, Kropf et al. disclose wherein the free end of at least one arm comprises a cutter having a beveled edge adapted to slice tissue (col. 3, lines 61-65).

Regarding claim 8, Kropf et al. disclose wherein each arm has an axial length from the fixed end to the free end, and wherein the axial length of at least one arm is greater than the axial length of the other arms (1 of fig. 2). However, Kropf et al. do not disclose wherein the axial length of the at least one arm comprising the tooth is greater than the axial length of the other arms. Ambrose discloses wherein the axial length of the at least one arm comprising the tooth is greater than the axial length of the other arms (page 1, lines 79-86). At the time of the invention, it would have been obvious to one skilled in the art to design the axial length of the at least one arm comprising the tooth to be greater than the axial length of the other arms, as taught by Ambrose. The motivation for doing so would have been to grasp an excised tissue sample without disturbing the sample.

Claims 14-15 and 17 lack an inventive step under PCT Article 33(3) as being obvious over Kropf et al. (US 5,522,825) in view of Kogasaka et al. (US 6,371,968).

Regarding claim 14, Kropf et al. do not disclose wherein a portion of the patient's ligamentum flavum occupies the region of interest, and wherein step c) comprises inserting the tissue excision device into the ligamentum flavum in the region of interest, step d) comprises cutting at least a portion of the ligamentum flavum in the region of interest, and step e) comprises removing at least a portion of the cut ligamentum flavum. Kogasaka et al. disclose a medical procedure wherein a portion of the patient's ligamentum flavum occupies the region of interest, and wherein step c) comprises inserting the tissue excision device into the ligamentum flavum in the region of interest, step d) comprises cutting at least a portion of the ligamentum flavum in the region of interest, and step e) comprises removing at least a portion of the cut ligamentum flavum (col. 1, lines 28-37). At the time of the invention, it would have been obvious to one skilled in the art to use the tissue excision device on a portion of the patient's ligamentum flavum, wherein step c) comprises inserting the tissue excision device into the ligamentum flavum in the region of interest, step d) comprises cutting at least a portion of the ligamentum flavum in the region of interest, and step e) comprises removing at least a portion of the cut ligamentum flavum, as taught by Kosaga et al. The motivation for doing so would have been to safely operate on the ligamentum flavum area of a patient's back.

Regarding claim 15, Kropf et al. do not disclose further comprising the steps of compressing the dural sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone in the region of interest, the safety zone lying between the working zone and the dural sac. However, Kogasaka et al. disclose further comprising the steps of compressing the dural sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone in the region of interest, the safety zone lying between the working zone and the dural sac (col. 1, lines 54-63). At the time of the invention, it would have been obvious to one skilled in the art to compress the dural sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone in the region of interest, the safety zone lying between the working zone and the dural sac, as taught by Kogasaka et al. The motivation for doing so would have been to safely operate on a dural sac of a patient's back.

Regarding claim 17, Kropf et al. disclose a tissue excision device comprising: an outer sleeve (7 of fig. 2); an inner tubular member slidingly received within the outer sleeve (col. 4, lines 23-24); a cutting head on a distal end of the inner tubular (10, 11, 4); wherein the cutting head comprises at least three arms extending axially from the inner tubular (10, 11, 4; see also col. 2, lines 61-62); wherein the device has an open position in which the cutting head extends from the outer sleeve, and a closed position in which the cutting head is at least partially disposed within the sleeve (col. 3, lines 44-65). Kropf et al. do not disclose a kit for performing a procedure on a spine, the spine including an epidural space containing a dural sac, the kit comprising: an insertion member for accessing the epidural space; a volume of a contrast medium adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the dural sac and provide a safety zone within the epidural space. Kogasaka et al. disclose an insertion member for accessing the epidural space (col. 10, lines 19-21); a volume of a contrast medium adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the dural sac and provide a safety zone within the epidural space (col. 1, lines 54-63). At the time of the invention, it would have been obvious to one skilled in the art to combine the tissue excision device of Kropf et al. with an insertion member for accessing the epidural space; a volume of a contrast medium adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the dural sac and provide a safety zone within the epidural space, as taught by Kogasaka et al. The motivation for doing so would have been to access the dural space during surgery in a minimally invasive manner.

Claims 1-17 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in the industry.